The percutaneous Greenfield filter: Outcomes and practice patterns

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Objective: **The percutaneous steel Greenfield filter (PSGF) is similar in appearance to the titanium Greenfield filter (TGF) but differs in the length and orientation of the attachment hooks and in the over-the-wire delivery system. Because these differences improve ease of insertion and attachment, they may affect patient outcomes and physician practices. The purpose of this study was to evaluate the performance of the PSGF relative to the TGF and to determine whether there had been a change in physician practices.**

Methods: **The Michigan Filter Registry contains data for a prospective cohort of 2188 patients with Greenfield filters. Procedural and long-term outcomes for patients with a PSGF were abstracted. These events were compared with rates for Registry patients who had a TGF. Trends for indication for placement, delivery route, and filter location were also compared with published series.**

Results: **Since 1995, 600 PSGFs have been placed in 599 patients. A 1-year mortality rate of 42% left 349 patients available for annual follow-up, and studies were completed for 231 (66%). Periprocedural events occurred in 2.5% of cases with associated morbidity in 1.5%. The rate of new pulmonary embolism was 2.6%, and vena caval patency was 98.3%. The combined rate of new venous thromboembolic events was 12.5%. Left-sided femoral vein placements increased to 20%, and the major indication for filter placement has become prophylaxis (46%).**

Conclusions: **The PSGF is similar to the TGF with respect to patient outcomes, and it provides decreased rates of asymmetry along with excellent fixation. The flexible carrier system has allowed more frequent access through the left femoral vein. The ease of use and favorable patient outcomes have resulted in more frequent placement for prophylactic indications. (J Vasc Surg 2000;32:888-93.)**

Vena caval filters are a widely accepted method of prevention of pulmonary embolism (PE), and one of the driving forces for improvement has been ease of percutaneous insertion. This was the impetus for the development of the titanium Greenfield filter (TGF), which used a 12F carrier system as opposed to the 24F system used for the operative insertion of the original stainless steel Greenfield filter (SGF). The TGF has proved comparable to the SGF in the long term with regard to vena caval patency (99%) and protection from PE (97%).[1,2]

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Because of design constraints, the guidewire was eliminated during insertion, and this may have been responsible for the 10% incidence of asymmetry of the limbs that was observed. One possible cause for the asymmetry was a failure of centering in the cava in the absence of a guidewire at the time of filter release. Even though there was no correlation between asymmetry of the limbs and recurrent embolism, it represented a theoretical opening for small emboli on the basis of experimental modeling.[3] For the guidewire technique to be restored, a stainless steel filter was designed with a longer neck that accommodated a guidewire yet only required a 12F carrier system. The guidewire and a new flexible carrier also facilitated placement from the left and right femoral veins.[4] The hooks were shortened from .05 to .035 in, and the vertical direction was altered in two limbs to accommodate the guidewire (Table I). Although these design changes were subtle, there was a potential for adverse effects. This study was undertaken to evaluate the effects on indications for placement and effectiveness of the percutaneous steel Greenfield filter (PSGF).

Table I. Characteristics of the titanium and steel percutaneous filters

	TGF	*PSGF*
Material	Titanium	Stainless steel
Hook	Modified obtuse	Alternating
Filter base diameter	38 mm	32 mm
Height	50 mm	52 mm
Delivery system	Steel carrier	Flexible carrier
Guidewire	No	Yes

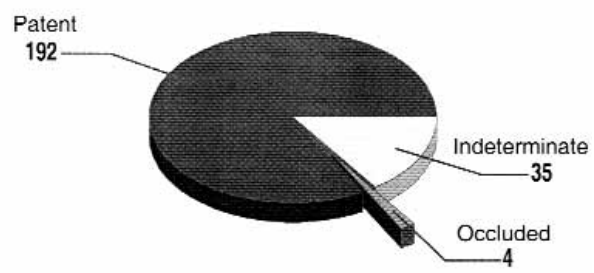

Fig 1. Long-term follow-up of PSGF patients for caval patency.

MATERIAL AND METHODS

The Michigan Filter Registry contains data collected at the time of filter insertion and annually scheduled follow-up visits. Data are classified into three categories: demographic and clinical status at time of filter placement, details of the placement, and patient and filter findings at the yearly follow-up visits and unscheduled hospital admissions. All data are collected by one reviewer on the basis of the medical record. Patients are contacted each year with a reminder letter for their follow-up examination, which includes physical examination, ultrasound scan of the inferior vena cava and bilateral lower extremities, and plain radiograph of the abdomen obtained in anteroposterior and lateral projections. When a patient is reported to have died, efforts are made to obtain the cause of death from the hospital record or the next of kin. The database was queried for all patients with a PSGF as their primary or secondary device. The reporting standards for vena caval filters of the International Society for Cardiovascular Surgery and the Society of Cardiovascular and Interventional Radiology[5,6] were used to summarize the data. Outcomes were compared with those previously reported or as summarized from the Registry[1] with SAS version 6.12 (SAS Institute Inc, Cary, NC). χ^2 Tests were used for dichotomous data and *t* tests or analysis of variance for continuous outcomes. *P* values less than .05 were considered significant.

Table II. Effect on mechanical stability of the PSGF from modification of the fixation hook

	PSGF with alternating hook	*PSGF with standard hook*
Migration	0.4%	27%*
Penetration	1%	11%*
Increase filter base	0.4%	5%
Tilt	0.4%	5%
Asymmetry	2%	5%

*$P < .05$.

Table III. Primary diagnoses among patients with PSGF

Trauma	28.3%
Surgery	22%
Venous disease	17.2%
Malignancy	13.5%
Cardiac disease	3.2%
Pulmonary disorder	2.8%
History of PE	2.7%
Arterial disease	1.5%
CNS disorder	1.2%
GI	1%
Pregnancy	1%
Other	5.6%

CNS, Central nervous system; *GI,* gastrointestinal; *PE,* pulmonary embolism.

RESULTS

The PSGF accounts for 31% of database entries with 600 filters in the 299 women and 300 men (mean age, 54 years). The mean time for data accrual was 26 months. Thirty-day and 1-year mortality rates were 13% and 42%, respectively. Death was related to the underlying disease in all but one case. This patient died 2 days after filter placement with PE listed as the cause of death. No autopsy was performed. Annual follow-up was obtained in 231 (66%) of 349 eligible patients surviving at 1 year. Of these, 213 had the revised alternating hook PSGF, whereas 18 had an earlier version of the device modeled after the TGF hooks, which were recurved to an angle of 80 degrees. This revision allowed some distal migration, and therefore, two of the six hooks were directed downward at an angle of 125 degrees for further stabilization (Table II).

Patient characteristics. Surgery (22%), trauma (28%), venous disease (17%), and malignancy (13.5%) were the most frequently recorded primary diagnoses (Table III), and contraindication to anticoagulation (34%) and prophylaxis (46%) comprised 80% of place-

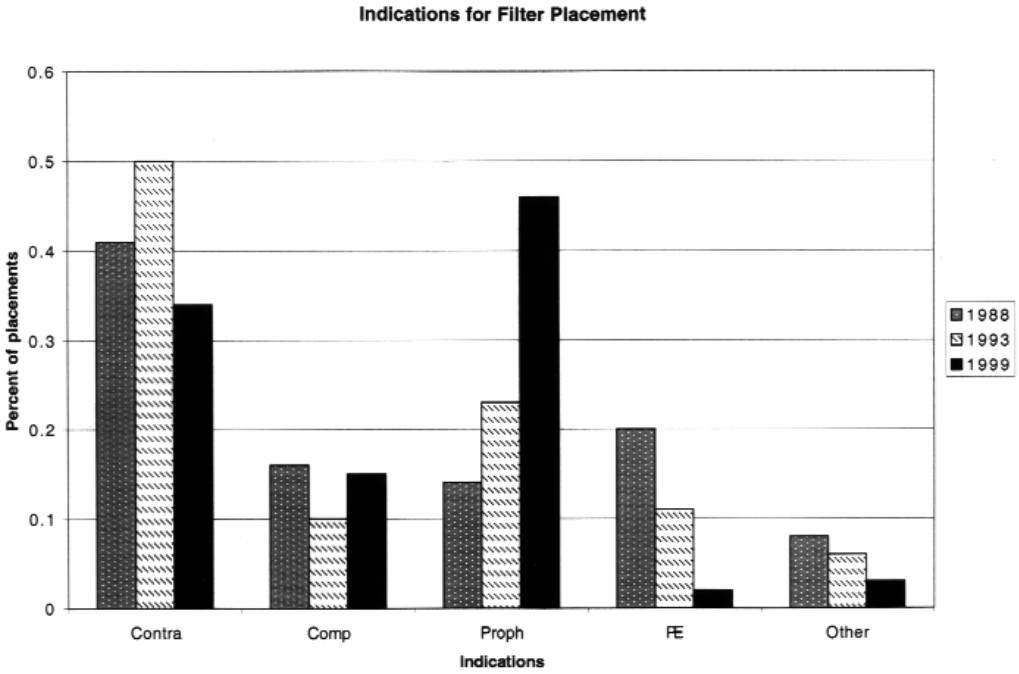

Fig 2. Changing indications for filter insertion from 1988-1999. The most dramatic increase occurred in the indication prophylaxis.

ment indications (Table IV). Anticoagulants were used by 282 patients before placement, whereas 266 were anticoagulated subsequently. Filters were most often placed by radiologists (590 of 599), and all but two were placed percutaneously. More than 70% were placed through the right femoral vein and 10% through the right jugular vein. The flexible delivery system facilitates placement from the left groin, which allowed radiologists to use this preferred access. The number of left femoral vein insertions increased to 20% with no accompanying increase in insertion site problems. All but two attempts at placement were successful (99.6%). Filters were placed above the renal vein in 5% of patients (Table V). Insertion problems occurred in 16 patients, including incomplete opening, asymmetry, tilt, sheath kinking, and leg crossing. The postprocedure complication rate was 1.5% with two hematomas and seven bleeding episodes.

Follow-up summary. Long-term event rates are based on the 231 patients who had objective follow-up. Most significantly, recurrent PE was seen in six patients (2.6%), five of whom were also being anticoagulated. Four filters (1.7%) were occluded, on the basis of absent Doppler scan signal and the inability to visualize the filter (Fig 1). Ultrasound scan of the inferior vena cava was indeterminate in 35 patients because of less than optimal examination results, but none of these patients had signs or symptoms of caval occlusion. There were 14 new isolated cases of deep venous thrombosis (DVT), four cases of DVT that occurred with PE or caval occlusion and 10 asymptomatic insertion site thromboses for a recurrent thromboembolism incidence of 12.5%. Abdominal radiographs were obtained for 223 (97%) of 231 patients. Filter movement greater than 20 mm was noted in 3% total but in only 1% of the alternating hook design. Asymmetry was reported in five patients (2%). Penetration of the vena cava by a filter limb was suspected in four patients, and computed tomographic scans of the four confirmed two asymptomatic penetrations.

Sixty-two patients (27%) had lower extremity edema at follow-up, and 37 used graduated support stockings to control the symptoms. Ulceration occurred in six patients (2.6%). Anticoagulation was used by 76% of the patients at some point between filter placement and clinical follow-up, and 81 continued to require anticoagulation at their last examination.

DISCUSSION

Improvements in the mechanical properties of the Greenfield filter have been achieved by changing the metal alloy, as with the titanium model, or the design, as with the PSGF. These modifications added

the flexibility needed to fold the device into a smaller carrier for percutaneous insertion. However, these changes also reduced the force of attachment to the vena caval wall, which necessitated a change in hook configuration. With the TGF, the more obtuse angle achieved good fixation, but it proved inadequate when a slightly shorter version was used in the PSGF. Alternating the hooks in a downward and upward direction achieved optimal stabilization. Initial experience with the PSGF was reported in 75 patients from nine participating institutions with a 30-day follow-up.[7] This showed a reduction in the 10% asymmetry rate seen with the TGF to 5.3% ($P = .28$) with no clinical sequelae. There were no recurrent PE episodes in the abbreviated follow-up, but caval occlusion was seen in three patients with end-stage metastatic disease (5%). There was one instance of probable caval penetration without sequelae. There was no migration beyond the accepted respiratory variation limits of 20 mm. An additional report of 47 patients by Johnson et al[8] showed a 2% recurrent PE rate but a 12% (2 of 16) incidence of caval thrombosis. Filter asymmetry was reported in 14 patients.

The PSGF was never envisioned as an improvement to the TGF but as an alternative. Table I lists some minor differences in materials and design that may lead to selection of one over the other in various situations. There are two major differences: the flexible carrier and the availability of a guidewire. The flexible carrier led our radiologists to pursue the left femoral route in a larger percentage of placements because they prefer a groin to a neck approach. From a clinical perspective, this has resulted in fewer insertion-site thromboses. The differences in caval patency and new DVT are more likely related to the differences in the patient groups because the rate of prophylactic placements doubled since 1993.

In the current article, we have insertion and follow-up data on a much larger group of PSGF patients, which show a reduction in the incidence of asymmetry from 10% to 2.1% ($P = .03$). These differences in rates among reporting centers highlight the need to develop standard definitions for technical events to allow adequate comparison. The recurrent rate of PE with the PSGF is neither clinically nor statistically different than the TGF (3.5%) or the SGF (4%)[1,2] (Table VI). Recurrent PE is an indication for a venacavogram to visualize the filter that usually has successfully trapped thrombi but may have propagating thrombus above it. When this is documented, either lytic therapy should be used or a second filter should be inserted in a suprarenal position, as it occurred in one patient in this series. Filter occlusion occurs from a large volume of trapped thrombus and was noted previously in 3.6% of SGF patients, 3.5% of the TGF patients, and only 1.7% of patients in the current series. New or recurrent DVT occurred in 17 patients (7%), whereas 10 (4.3%) had thrombosis of their insertion site. Aggregating these with the patients with recurrent PE produces an overall rate of 12.5% of recurrent thromboembolic disease in this series. Recurrent thrombosis in filter patients has been erroneously attributed to the presence of a filter,[9] rather than the more likely underlying thrombotic disease. However, most series show even higher recurrence rates in patients with DVT without filters.[10]

Two technical problems have been cited in published reviews.[4,11-14] The first is related to incomplete opening of the filter at deployment. Review of the reports indicated that when the original carrier was retracted, it failed to completely uncover the filter hooks. This happened when the carrier length was at the upper limit of design tolerance. The manufacturer lowered the tolerances, and reports of this

Table IV. Indications for placement of PSGF

Prophylaxis	46%
Contraindication to anticoagulation	34%
Complication with anticoagulation	15%
Recurrent PE	2%
Unknown	3%

Table V. Location and route for PSGF placement

Location	
Infrarenal	569 (95%)
Suprarenal	30 (5%)
Route	
Left femoral	118 (19.6%)
Right femoral	413 (69%)
Right jugular	61 (10%)
Other	7 (1%)

Table VI. Comparison of outcomes for patients with percutaneous Greenfield filters

	PSGF	*TGF*
New PE	2.6%	3.2%
Caval patency	98.3%	93.2%
New DVT	7.3%	15%*
Insertion site thrombosis	4.3%	8.4%
Migration	1%	1%
Asymmetry	2%	10%*
Fracture	0.3%	0
Ulceration	2%	5%

*$P < .05$.

problem declined. The second problem involved entrapment of guidewires by the filter at deployment and during other interventional procedures. Design changes to the PSGF reduced the space between the struts at the apex of the filter and included an opening for a guidewire. If the wire looped back on itself or kinked, it could become trapped between the struts and resist removal. Kaufman et al[15] have reported results from an in vitro study indicating this occurs with J wires less than 3-mm in circumference. They recommend that a 15 J guidewire be used whenever blind central line procedures are performed. Visualization of guidewire extraction at the time of filter placement, use of fluoroscopy during line changes in patients with vena caval filters, and cessation of guidewire pulling when resistance is encountered until adequate visualization is available will limit morbidity.

With improved ease of insertion provided by the reduced delivery system and the flexible carrier, we began to see a change in indications because clinicians seemed more willing to insert a filter than to risk anticoagulation in borderline situations. More patients are receiving filters for "prophylaxis" than for other indications related to anticoagulation. Where 89 (14%) of 616 filters placed before 1988 were for prophylaxis, 90 of 388 filters placed between 1988 and 1993 were prophylactic, and in 1999, the percentage rose to 46% or 276 of 600 filters. The interpretation of prophylaxis has now broadened to include patients with or without currently documented DVT or PE and those in whom the filter is used as an adjunct to anticoagulation. The most dramatic increase has been in the prophylactic use of the filter in patients with trauma, which accounts for 51% of all prophylactic placements (Fig 2). The evidence supporting this approach has been based on clinical experience in which a series of high-risk patients who have trauma with filters were compared with historical controls.[16-18] These high-risk patients showed excellent protection from use of the filter, but with PE rates of 1% or less, most patients do not develop DVT or PE. Therefore, they did not directly benefit from the procedure. There is a clear need for a method of risk assessment that will concentrate this costly investment in a population of patients with trauma who are most likely to benefit from it.

The PSGF is a safe and effective means of preventing PE. Design changes in the delivery of the device, the fixation hooks, and the apex wires, along with its record of efficacy, have led to more frequent prophylactic placements. Continued long-term study of these patients is warranted to determine the effects of these modifications.

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DISCUSSION

Dr Robert Rutherford (Silverthorne, Colo). I have a few comments before posing four questions to the authors. As you have heard from the presentation here, the focus of this paper goes well beyond changing practice patterns. It brings valuable performance data on the percutaneous stainless steel Greenfield filter, documenting the performance and what can be expected from this new technological advance. This may be, in a way, the most impressive part of the paper. Also significant is the depth of data in this performance analysis, which is generated by a registry geared to the new reporting standards for caval filters. I would hope in the future that reported experiences with this and other caval filters will comply with these standards and give us equally objective and detailed disclosure of outcomes.

I have the following questions for Dr Greenfield. First, you report a 1-year mortality of 42%, which may not be surprising, considering the high-risk groups represented, particularly the trauma group. Is there any way of getting representative early performance data on some of these lost patients? If not, do you think the exclusion of these high-risk cases from the later 1-year follow-up potentially improves the performance data that you report?

Second, can you tell us something about the Michigan Filter Registry? Is it just for Greenfield filters? How many participating centers are there? Do you analyze the feedback to see whether it is representative of a broader nationwide performance with this new filter?

Third, there are several design changes represented in the new percutaneous device, and I would like to ask you how you would rank them in the performance advantages that you have documented here today. I know there is reduction from a #24 to a #12 French introducer, the flexible carrier, the over-the-guidewire insertion and release, and some other subtle design features of the filter itself. What do you feel are the relative roles they play in how well this new filter is doing?

Finally, along the same lines, how much do the changing indications, which are now mostly prophylactic use, contribute to the better performance of the newer percutaneous version? In other words, are the changes in practice pattern self-generated, or are they a result of the new improvements in the filter? How much do these changes in practice influence a better performance, since they are mostly for prophylactic indications?

Finally, in closing, I would like to add a comment about the increasing prophylactic use. In your manuscript you identify, and I quote, "a clear need for a method of risk assessment that will concentrate on this most costly investment in a population of trauma patients most likely to benefit from it," and I would certainly echo this. I would further suggest that we need randomized comparisons of outcomes that include cost-benefit analysis that are stratified for these new prophylactic indications, particularly trauma, cancer patients, and so forth. I enjoyed the paper very much. I think it brings us valuable and well-analyzed data on the new filter, as well as characterizing associated practice changes. Thank you for the privilege of the floor.

Dr Lazar J. Greenfield. Thank you very much for your insightful questions. Your first question was about the accuracy of the information that we have related to patients who died. Obviously the most accurate information we have is on patients who die in the hospital since we would have any subsequent scans, angiograms, or CT, that would have suggested thromboembolic events. For deaths that occur outside of the hospital, we have to rely on information that we get from the family or the referring physicians, and that is, as you know, quite unreliable. We do try, with all these patients, to determine whether or not there was any chance that the patient sustained a pulmonary embolic death or any death related to the filter, and we have reported any of those that we thought could have been related.

The second question was about the filter registry. The Michigan Registry that we maintain is only the Michigan experience. We do have a few other filters in it, the occasional bird's nest that the radiologist inserts for the mega cava. There is a potential difference between our experience and other institutions in the areas of asymmetry and tilting because there are no consistent standards. That is one of the reasons that we were stimulated to develop the reporting guidelines that have been published.

The next question was the importance of the design changes. I think that clearly the most significant advantage was in size of the carrier system, reducing it from #24 to #12 French, allowing for percutaneous insertion. This really made a dramatic change in the perceived ease of positioning the device. As far as the other changes, the hook configuration seems to be most important in terms of the performance of the device, that is, its long-term stability.

Finally, your last question, does more prophylactic use contribute to improved performance? We were concerned about that. We looked at the embolic events in the prophylactic group alone, which had no evidence of the thrombotic disorder at the time of placement, and indeed the recurrent embolism rate was 2.2% in this group as opposed to 2.4% in the treatment group, showing that there was very little difference. So there may be an influence, but so far we have not been able to see it.